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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	20

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,516	LO ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6 and 10-14* is/are rejected.

7)☒ Claim(s) *4,7-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is a response to the "Reply to Office Action..." filed 13 June 2003 (Paper No. 19) in reply to the Non-Final Office Action mailed 10 March 2003 (Paper No. 18). Claims 1-14 were considered in Paper No. 18. Claims 1, 3, 7, 8, 10, 13 and 14 were amended in Paper No. 19. Claims 1-14 are pending and under consideration.

Response to Amendment

Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record in Paper No.'s 7 and 15 and herein below in the "Response to Arguments".

Claims 1-3, 5, 6 and 10-14 stand rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the claimed subject matter for reasons of record and herein below in the response to arguments. Please note, although the rejection was not applied to claim 11 in Paper No. 18, it is clear that the vector of the claim is not limited to comprising a protein involved in replication of the lactic acid bacterial plasmid that is adequately described in the disclosure. Therefore, the written description rejection of record in Paper No. 18 is hereby applied to claim 11.

Rejection of claims 4 under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the claimed subject is withdrawn. Applicant argues persuasively that a marker gene that is not an antibiotic resistance gene was conventional in the art at the time of filing.

Rejection of claims 1, 7, 8, 10 and 11 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn.

Response to Arguments

Claim 13 is rejected as lacking enablement for the broad scope of "an antigenic gene". In response to the arguments of record, Applicant cites *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC 1988) in arguing that the amount of experimentation required to make the full scope of the invention is not undue because a considerable amount of experimentation is permissible, if it is merely routine. Applicant argues that methods of determining the efficacy of a vaccine are well known and routinely practiced in the art and that determining whether a Lac shuttle vector carrying an antigenic gene would be effective in inducing a protective immune response can be determined using these methods as routinely practiced by the skilled artisan.

These arguments have been fully considered but are not found persuasive. First, *In re Wands* also provides, "[t]he determination of what constitutes undue experimentation in a given case requires the application of standard reasonableness, having due regard for the nature of the invention and the state of the art" (*Id.* at 1404). The factors to be considered in determining whether the quantity of experimentation is undue include the breadth of the claims, the level of predictability in the art, the amount of direction or guidance presented, the presence or absence of working examples and the state of the prior art. As pointed out in previous office actions, the instant claims are extremely broad, encompassing a DNA vaccine composition comprising any antigenic gene inserted into the described vector. It is also established in previous office actions that there is a high degree of unpredictability in the art (see especially pages 8 and 9 of the Office

Action mailed 27 November 2001) and that the teachings in the specification would not enable the skilled artisan to identify the enabled embodiments of the claimed invention without having to resort to blind trial and error experimentation to make and test each and every construct encompassed by the claim. Further, it has been pointed out that the courts have held that claims might lack enablement if the number of inoperative combinations of a claimed invention become significant, and in effect force one of ordinary skill in the art to experiment unduly in order to practice the claimed invention (see the paragraph bridging pages 3-4 in Paper No. 18). Clearly, given the breadth of the claims and the unpredictability of the art, determining which embodiments that were conceived, but not yet made, would be inoperative or operative would require expenditure of more effort than is routine in the art.

Claims 1-3, 5, 6 and 10-14 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for "a nucleic acid sequence encoding a protein which is involved in replication of the lactic acid bacteria plasmid". In response to the rejection of record Applicant argues that the full scope of nucleic acids encoding a protein which is involved in replication of the lactic acid bacteria plasmid is described by the example of a nucleic acid encoding RepA disclosed in the specification and teachings of other proteins related to replication of lactic acid bacterial plasmids in the art. In support of this argument, Applicant cites four studies.

The arguments and evidence provided have been fully considered but are not found persuasive. Firs, it should be pointed out that the nucleic acid of the claims encodes any protein *involved in* replication of the lactic acid bacterial plasmid. As the specification provides no limitation on how the protein might be involved in replication of the lactic acid bacterial plasmid,

the protein of the claims encompasses any protein that might be considered to be involved in replication of the plasmid. For example, replication of a plasmid is an energy dependent process; therefore, proteins involved in energy production in the lactic acid bacterial plasmid are also involved in replication of the plasmid. The teachings from the art cited by applicant are limited to nucleic acids that, like *repA*, are naturally occurring in lactic acid bacterial plasmids and encode related proteins. Katani *et al.* teaches that the OrfA-encoded protein disclosed therein is homologous to the replication protein of a plasmid found in *P. halophilus* (see especially the second column on page 129). Klein *et al.* teaches that the gene product of ORF2, disclosed therein, is homologous to the pMV or pLS1 replication proteins and RepA (see especially the second full paragraph on page 23). However, the protein involved in replication of the lactic acid bacterial plasmid of the instant claims is in no way limited to occurring naturally on lactic acid bacterial plasmids or being structurally related to the proteins disclosed in the art. As the scope of the claims goes well beyond what is disclosed in the cited art, the art fails to adequately support the claimed subject matter. Thus, the claims stand rejected as lacking adequate written description.

Allowable Subject Matter

Claims 4 and 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms

JAMES KETTER
PRIMARY EXAMINER